

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

IN RE: TESTOSTERONE REPLACEMENT  
THERAPY PRODUCTS LIABILITY  
LITIGATION

MDL No. 2545

Master Docket Case No. 1:14-cv-01748

Honorable Matthew F. Kennelly

This document relates to:

*Konrad v. AbbVie Inc.*, No. 1:15-cv-00966

**PLAINTIFFS' PROPOSED PRELIMINARY JURY INSTRUCTION REGARDING FDA**

Pursuant to the Court's instruction, Plaintiffs hereby propose that the Court provide the following instruction regarding the Federal Food and Drug Administration:

***Plaintiffs' Proposed Preliminary Jury Instruction:***

***Role of Federal Food and Drug Administration (FDA)***

Under the law, a manufacturer, in this case AbbVie, bears ultimate responsibility for the content of its label at all times. AbbVie is charged both with crafting an adequate label and with ensuring that its warnings remain adequate for as long as the drug is on the market.

Furthermore, AbbVie can unilaterally add or strengthen a warning, precaution, contraindication, or adverse reaction for its products without prior FDA approval. In that regard, a manufacturer is not only allowed to do so but is required to revise its label to include a warning as soon as there is reasonable evidence of a causal association of a serious hazard with its drug; a causal relationship need not have been definitely established before a manufacturer is required to change its warnings. Changes to a product's warnings by a drug manufacturer can be initiated on the basis of newly acquired information, or on the basis of new analyses of earlier information. Risk information accumulates over time and that same data may take on a different meaning in light of subsequent developments. In considering the information available to AbbVie, you may properly consider what was known, or what should have been known, about the risks of AndroGel.

*Source: Wyeth v. Levine, 555 U.S. 555 (2009); 21 CFR § 201.80(e); 21 CFR §314.80.*

*Approved:* \_\_\_\_\_

*Denied:* \_\_\_\_\_

*Modified:* \_\_\_\_\_

*Withdrawn:* \_\_\_\_\_

Date: June 8, 2017

Respectfully submitted,

/s/Christopher A. Seeger

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 8, 2017, the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

*/s/ Brendan A. Smith* \_\_\_\_\_  
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